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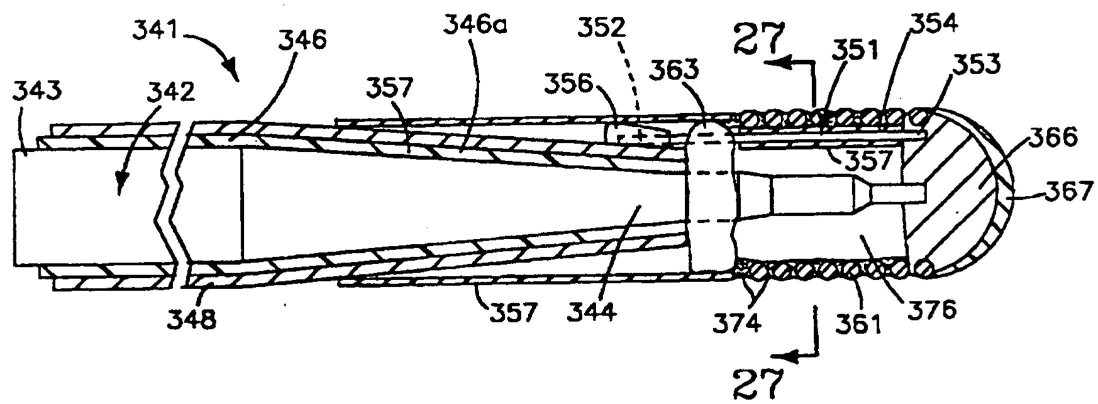

(57) Abstract

This invention is a guide wire for use in a medical procedure and for use with a power supply (426) comprising a solid core wire (342) having proximal (343) and distal extremities (344). The proximal extremity (343) has a predetermined diameter. At least a portion of the distal extremity (344) has a reduced size with respect to the predetermined diameter. A flexible coil (361) is secured to the distal extremity (344) of the core wire having a reduced size. An actuator member (351) is disposed proximal of the coil (361) and extends along the core wire (342). Electrical conductors (437) extend from the proximal extremity (343) of the core wire to the actuator member (351) for supplying heat to the actuator member (351). The actuator member is formed of a temperature activated metal alloy having a Young's modulus of 4 x 1,000,000 psi to 14 x 1,000,000 psi which increases in stiffness when heat is supplied thereto to increase the stiffness of the guidewire proximally to the coil.

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GUIDE WIRE WITH ADJUSTABLE STIFFNESS AND METHOD

This invention relates to guide wires with adjustable stiffness and method and more particularly to guide wires having adjustable stiffness tips and adjustable deflection guide wires having adjustable stiffness shaft portions for supporting stents.

Guide wires have been available in the past for many different applications including medical applications such as coronary angioplasty. In guide wires heretofore provided for angioplasty applications, such guide wires have been provided with flexible tips which typically can be shaped outside the body and then introduced into the body. With such a procedure it is often necessary to remove the guide wire from the body and reshape the distal extremity and reinsert the guide wire into the body to negotiate a tortuous vessel. Also, with such guide wires, the tips of the guide wires had insufficient stiffness to cross lesions which occlude or substantially occlude vessels. Guide wires for helping deliver stents have been provided with a stiffer distal extremity in order to achieve the stiffness required to place the stent in the desired location. When such a guide wire is provided with such stiffness, it is difficult to utilize such a guide wire for initially entering the vessel. This is true because

with such guide wires it typically has been desirous that the tips be very floppy so that they can negotiate tortuosities encountered in the vessel. This often has made it necessary to utilize two guide wires in a single procedure, one guide wire being utilized having a floppy distal extremity for directing the guide wire into the desired location after which the floppy guide wire is removed and the other guide wire having a stiffer distal extremity being utilized for positioning a stent in the desired location. Therefore there is a need for a guide wire that does not have such limitations. Also, there is a need for providing a guide wire which can have a very floppy distal extremity and which can thereafter be made stiffer to aid in positioning a stent in the desired location.

In general, it is an object of the present invention to provide a guide wire which has an adjustable stiffness and method.

Another object of the invention is to provide a guide wire and method of the above character in which an adjustable stiffness is provided in the tip of the guide wire.

Another object of the invention is to provide a guide wire and method of the above character in which an adjustable stiffness is provided in a portion of the shaft of the guide wire to provide an adjustable support characteristic.

Another object of the invention is to provide a guide wire of the above character in which a sleeve of a superelastic material is provided at the distal extremity for adjusting stiffness.

Another object of the invention is to provide a guide wire of the above character which initially can have a very floppy distal extremity.

Another object of the invention is to provide a guide wire and method of the above character which can be utilized for deploying a stent.

Another object of the invention is to provide a guide wire of the above character which can be adjusted to provide additional support to aid in delivering a stent and which does not readily collapse or prolapse and does not resist placement of a stent delivery catheter.

Another object of the invention is to provide a guide wire and method of the above character which can be utilized with a balloon stent delivery catheter in which the guide wire provides strong mechanical support for deployment of the balloon and the stent.

Another object of the invention is to provide a guide wire and method of the above character in which additional stiffness can be imparted to the distal extremity to facilitate penetration of a stenosis in a vessel.

Another object of the invention is to provide a guide wire and method of the above character in which localized heating is utilized to minimize the introduction of heat into the bloodstream in the vessel.

Another object of the invention is to provide a guide wire and method of the above character in which various degrees of floppiness can be achieved in the distal extremity.

Another object of the invention is to provide a guide wire and method of the above character in which the tip can be deflected in substantially real time.

Another object of the invention is to provide a guide wire and method of the above character in which coaxial conductors are utilized to maximize the size of the coil wire, to reduce any tendency to whip and to facilitate manufacture.

Additional objects and features of the invention will appear from the following description in which the preferred embodiments are set forth in detail in conjunction with the accompanying drawings.

Figures 1-18 are omitted because they are included in U.S. Patent No. 5,542,434.

Figure 19 is a sectional view of an embodiment of a guide wire incorporating the present invention in which additional stiffness can be imparted to a shaft portion of the guide wire.

Figure 20 is a cross-sectional view taken along the line 20-20 of Figure 19.

Figure 21 is a graph showing the support provided in the shaft portion of the guide wire and showing the change in support provided between activated and non-activated states.

Figure 22 is a sectional view of still another embodiment of the guide wire incorporating the present invention in which additional stiffness can be imparted to a shaft portion of the guide wire.

Figure 23 is a cross-sectional view taken along the line 23-23 of Figure 21.

Figure 24 is a sectional view of another embodiment of a guide wire incorporating the present invention taken along the line 24-24 of Figure 25.

Figure 25 is a cross-sectional view taken along the line 25-25 of Figure 24.

Figure 26 is a sectional view of still another embodiment of a guide wire incorporating the present invention in which a deflectable tip is provided.

Figure 27 is a cross-sectional view taken along the line 27-27 of Figure 23.

Figure 28 is a cross-sectional view similar to Figure 27 showing another embodiment of a guide wire incorporating the present invention.

Figures 29-32 are isometric views of additional embodiments of actuators incorporating the present invention which can be utilized in the guide wire shown in Figures 26 and 27.

Figure 33 is a schematic block diagram showing circuitry which can be utilized with the guide wires of the present invention for calibrating the guide wire.

In general, the guide wire of the present invention is for use in a medical procedure and for use with a power supply comprising a solid core wire having proximal and distal extremities, the proximal extremity having a predetermined diameter, at least a portion of the distal extremity having a reduced size with respect to the predetermined diameter, a flexible coil secured to the distal extremity of the core wire and extending over the portion of the core wire having a reduced size, an actuator member disposed proximal of the coil and extending along the core wire, electrical conductive means extending from the proximal extremity of the core wire and to the actuator member for supplying heat to the actuator member, said actuator member being formed of a temperature activated metal alloy having a Young's modulus of 4×10^6 to 14×10^6 psi which increases in stiffness when heat is supplied thereto to increase the stiffness of the guide wire proximally of the coil.

Another embodiment of a guide wire with adjustable stiffness incorporating the present invention is shown in Figures 19-20. As shown therein, the guide wire 261 consists of a flexible elongate member 262 in the form of a core wire 262 formed of stainless steel 304 having proximal and distal extremities 263 and 264. The core wire 262 is solid. The proximal extremity 263 of the core wire 262 is provided with a predetermined outside diameter as for example ranging from 0.010" to 0.032" and preferably a diameter of 0.012". The distal extremity 264 of the core wire 262 is centerless ground to provide portions of reduced diameter with respect to the predetermined outside diameter. Thus, the distal extremity 264 is provided with portions 264a, 264b and 264c of progressively reduced diameters, as for example 0.09", 0.0055" and 0.0025",respectively,and a flattened

distal portion 264d having a width of 0.0015" and a thickness of 0.0001". As shown, the portions 264a, 264b, 264c and 264d are cylindrical in shape with tapered transitions extending therebetween. The core wire 262 can be of a suitable length, as for example 135-275 cm. and preferably approximately 175 cm.

An insulating layer 266 formed of a suitable material such as a polyimide is provided on the outer surface of the core wire 262 and extends from the proximal extremity 263 leaving a small annular space 267 on the proximal extremity 263 free of insulation to the distal extremity 264 and just beyond the portion 264b. The insulating layer 266 can have a suitable thickness ranging from 0.003" to 0.002" and preferably approximately 0.0005". A conductive layer 268 overlies the insulating layer 266 and extends just slightly beyond the portion 264a. This conductive layer 268 can be formed of suitable material such as a silver conductive ink of the same thickness as the polyimide layer 266.

A cylindrical tube-shaped actuator member 271 is formed of a suitable material such as a temperature variable superelastic Nitinol or other superelastic ordered intermetallic alloy having a Young's modulus ranging from 4×10^6 to 14×10^6 psi. The material has a Young's modulus in a soft martensitic state of $4-6 \times 10^6$ psi and a stiff or austenitic state ranging from $10-14 \times 10^6$ psi. The actuator member 271 can have a suitable outside diameter of, for example 0.010" to 0.013" and preferably 0.0125" and 0.009" to 0.010" inside diameter to provide a wall thickness of 0.001" to 0.002" and preferably 0.00175". This actuator member 271 can have a suitable length, as for example from 3-10 cm.

In one embodiment of the present invention, the sleeve has a wall thickness of 0.0025" thinned down to a thickness ranging from 0.001" to 0.0015" by centerless grinding after which the sleeve is cut down to the

desired length and the edges rounded. Thereafter a mandrel of a suitable material such as stainless steel having the desired size is inserted into the sleeve 36. The mandrel is used to keep the tube or sleeve 36 straight and circular rather than oval-shaped or elliptical so that it will not deform during heat treatment as hereinafter described. Thus the mandrel can have an outside diameter of for example 0.0085" to 0.009". The sleeve 36 with the mandrel therein is placed in a conventional oven and heat treated for a period of time ranging from 30 to 60 minutes and preferably 20 to 30 minutes at a temperature ranging from 300° to 600°C and preferably 440°C. After this heat treating operation has been completed, the superelastic sleeve 36 is removed from the oven and quickly cooled, after which the mandrel is removed. The sleeve is relatively rigid prior to the heat treating operation, whereas after the heat treating operation hereinbefore described, the sleeve is very flexible and pliable. As is well known to those skilled in the art of superelastic materials, the elastic material before the heat treatment is in the austenitic phase at room temperature whereas after heat treatment it is transformed into the martensitic phase at room temperature. Thus, by the heat treatment step hereinbefore described, the superelastic material is transformed from the austenitic phase to the martensitic phase so it is quite floppy and flexible at room temperature and will only assume the austenitic phase and become stiff when subjected to heat as hereinafter described.

The proximal extremity 272 of the actuator member 271 after it is heat treated is slid over the silver conductive layer so that it is in electrical contact therewith and also is coupled to the core wire 262 through the conductive layer 268 and insulating layer 266. As shown, the distal extremity 273 of the actuator

member 271 extends distally just beyond the termination of the insulating layer 266. A small conductive metal coil 276 formed of a suitable material such as silver is placed within the distal extremity 273 of the actuator member 271. A tube 278 formed of a suitable insulating material such as a polyimide and having a suitable size as for example an inside diameter of 0.0130" and an outside diameter of 0.140" and a suitable length as for example 20.5 cm is slid over the actuator member 271 and over the conductive layer 268 to the proximal extremity of the portion 264a of the distal extremity 264 of the core wire 262. A platinum radiopaque tip coil 281 having a proximal extremity 282 and a distal extremity 283 is provided. The proximal extremity 282 abuts the distal extremity 272 of the actuator member 271 and is secured thereto by suitable means such as a silver solder which bonds the coil 281 to the actuator member 271 and to the interior coil 276. A hemispherical tip 286 is formed by solder 286 which bonds the distal extremity 283 of the coil 281 to the portion 264d of the core wire 262.

With the construction shown, it can be seen that there is provided an air gap 287 between the solder 284 at the distal extremity 273 of the actuator member 271 and the silver conductive layer 268. Thus, it can be seen that the distal extremity 273 of the actuator member 271 is electrically connected to the core wire 262 whereas the proximal extremity 272 of the actuator member 271 is electrically in contact with the conductive layer 268 so that the electrical means hereinbefore described can provide electrical energy to the conductive layer 268 and to the bare coil wire portion 267. The polyimide tube 278 serves to provide a smooth transition from the tip coil 281 back to the tapered core wire 262. It also serves to electrically isolate the electrical circuit which is formed to supply electrical energy to the actuator member 271. It also

acts as a thermal barrier from the heat generated in the actuator member when it is actuated electrically.

Operation and use of the guide wires shown in Figures 19 and 20 may now briefly be described as follows. The tip of the guide wire will be bent in a conventional manner in the shape desired by the physician. The guide wire can be advanced through an introducer into the vasculature of the patient, as for example into an arterial vessel in which a stenosis or lesion is present. Generally, the distal extremity of the guide wire can be very floppy, which floppiness is not substantially inhibited by the use of the tubular actuator member 271. This is true because the tubular actuator member 271 has a relatively thin wall thickness permitting it to flex. If it is desired to increase the stiffness of the distal extremity of the guide wire, it is merely necessary to supply electrical energy to the actuator member 271 from the controller 289. This can be accomplished by supplying a desired current level to the actuator member for a period of time to retain the stiffness of the actuator member 271. Since the mass of the actuator member 271 is relatively small, this stiffness is created substantially instantaneously in real time, for example within 1-2 seconds. The current supply can also be adjusted, for example from 200-280 milliamperes. As soon as current flow is terminated, the actuator member 271 cools permitting the guide wire to return to its natural floppy state in its distal extremity. Thus, it can be seen that there has been provided a guide wire in which the stiffness of the distal extremity can be greatly increased when desired.

In connection with the present invention, it has been found that several Nitinol alloys can be utilized. One which is found to be satisfactory is an Alloy K or shape memory alloy supplied by Raychem Corporation of Menlo Park, California. It is a ternary alloy, it is a copper-containing nickel-titanium alloy. However, it

has been found that its stiffness characteristics are less desirable than a binary superelastic alloy, which is identified as Alloy BB from Raychem Corporation of Menlo Park, California. By utilizing this Alloy BB, it has been found that optimum stiffness characteristics can be obtained when the guide wire is activated and the desired floppiness is obtained when the guide wire is not activated. In other words, before activation the guide wire acts in a manner similar to a conventional floppy guide wire, whereas when activated it acts as one of the stiffer guide wires presently in the marketplace.

In Figure 21 there is a graph showing the adjustable stiffness which can be achieved utilizing the BB alloy. This adjustable stiffness has been calibrated in bend force in grams versus a distance from the tip of the guide wire. Thus as shown, since the actuator member 271 is spaced a predetermined distance from the tip, as for example the 3 cm shown, the change in stiffness is set forth in conjunction with the length of the actuator member 271 from the 3 cm. Thus it can be seen in this region the activation of the 20.5 cm actuator member 271 of the guide wire has a floppiness as indicated by the non-activated line 291. A substantial increase in stiffness is shown when the actuator member 271 is activated as represented by the line 292 in Figure 21. As soon as the actuator member 271 is deactivated, the guide wire returns to its non-activated floppy state. Conversely, as soon as it is again activated, it returns to the activated state shown by line 292.

From Figure 21 it can be seen that the bend force in grams changes as a function of distance from the tip of the guide wire. Thus, for the first few centimeters, up to 3 cm. from the tip the guide wire is very floppy and there is no change when the actuator member 271 is actuated. As explained previously, this is because the Nitinol actuator member 271 does not extend to within 3

cm of the tip of the guide wire. In the non-activated state, the stiffness is relatively constant until another taper in the grind of the core wire is reached, after which because of the increased cross-sectional area of the core wire, the stiffness increases. When the actuator member 271 is activated, the stiffness of the guide wire along the length of the actuator member 271 increases dramatically, largely overcoming the effects of gradations in the grinding of the core wire.

It has been found that providing an actuator member in the form of a tubular member or hypotube is very advantageous. In addition to dramatically increasing the stiffness of the portion of the guide wire in which it is present, the tubular member or tube is also easy to manufacture and can be readily incorporated into the guide wire. It can be readily put in place with electrical connections being made to opposite ends of the same for activation with electrical energy. Even though the actuator member 271 in the form of a hypotube, it does in fact not stiffen the core wire in the vicinity of the actuator member because any small increase in stiffness can be readily compensated for by increasing the grind to provide a larger diameter air space between the core wire and the interior of the actuator member 271. Thus it can be seen that any increase in stiffness imparted by the tubular actuator member 271 can be compensated for by additional grinding of the core wire so that the overall stiffness of the guide wire remains the same in an inactivated condition. When activated as explained previously, the stiffness of the guide wire changes dramatically in the region in which the actuator member 271 is positioned.

If desired, as shown in the drawings a lubricous coating (not shown) of a suitable such as Teflon can be applied to the exterior surface of the guide wire 261 to enhance the capability of the guide wire 261 to

transverse vessels in the patient. The coating can have a thickness ranging from 0.0005" to 0.001".

Operation and use of the adjustable deflection guide wire 261 with adjustable support characteristic or adjustable stiffness proximal of the tip coil 276 may now be briefly described as follows. At room temperature, the distal extremity of the guide wire 261 is very floppy and has characteristics comparable to floppy guide wires presently in the marketplace. Let it be assumed that it is desired to perform a conventional angioplasty procedure in which an entry is made into the femoral artery of the patient and a guiding catheter is inserted therein. Thereafter, the guide wire 261 of the present invention is introduced into the coronary vessel of the patient through the guiding catheter in a conventional manner utilizing the floppy characteristics of the guide wire to pass through tortuosities if present in the vessel until the distal extremity is disposed in the stenosis or occlusion in the vessel. A conventional balloon catheter (not shown) can then be advanced over the guide wire 11 after it has been positioned in the desired location with the balloon catheter tracking the guide wire until the balloon has been advanced into the stenosis to be treated in the angioplasty procedure. The balloon of the balloon dilatation catheter can then be inflated one or more times to enlarge the opening through the stenosis.

Thereafter, let it be assumed that it is desired to place a stent in the stenosis to aid it in remaining open and so that restenosis will not occur, the balloon dilatation catheter can be removed leaving the guide wire 261 in place. A stent delivery catheter is then advanced over the guide wire 261.

In order to provide additional support for the stent delivery catheter, electrical energy is supplied to the Nitinol sleeve 271 from a power supply 56 to supply electric current directly to the Nitinol sleeve

271 to heat the same to a temperature above 55°C but below 100°C so that the superelastic alloy material in the sleeve 271 is transformed to the austenitic state to progressively stiffen the same as the temperature increases and to thereby progressively stiffen the distal extremity of the guide wire 261. This stiffening serves to prevent the distal extremity of the guide wire 261 from collapsing or prolapsing. The stent (not shown) is delivered into the stenosis by the stent delivery catheter. After the stent has been advanced over the stiffened guide wire 261, the stent can be positioned in a conventional manner and left in place and the stent delivery catheter removed after which the guide wire 261 also can be removed to complete the medical procedure.

By using the guide wire of the present invention, it is only necessary to utilize one guide wire because the guide wire has a distal extremity with an adjustable support characteristic or adjustable stiffness in that it can be very floppy at room temperature or at the temperature of the human body when in blood in a vessel. It can be stiffened to provide additional support during the time it is desired to deliver a stent by supplying electrical energy to the Nitinol sleeve or actuator member 271 to heat the same. It should be appreciated that if desired, rather than supplying electrical energy directly to the stent, electrical energy can be supplied to a heating element (not shown) either on the inside or on the outside of the sleeve to heat the same to also cause it to assume an austenitic or stiff characteristic.

From the foregoing, it can be seen that there has been provided a guide wire with adjustable stiffness in which the stiffness is provided in a portion of the shaft of the guide wire proximal of the coil tip. It is also feasible to provide variable or adjustable stiffness in the tip in the same guide wire as well as

in adjustable stiffness proximal of the tip. Such a guide wire 301 is shown in Figures 22-23 and consists of a core wire 302 having proximal and distal extremities 303 and 304, respectively, and being sized and ground in the same manner as the core wire 262. It can have a suitable length, as for example ranging from 140-300 cm. An insulating layer 306 formed of a polyimide is provided on the exterior surface of the core wire 302. The polyimide insulating layer 306 can have a suitable thickness as for example 0.005". A conductive ink layer 307 is provided on the insulating layer 306.If desired, an insulation layer (not shown) can be provided over the conductive ink layer 317.

A first actuator member 311 in the form of a tube formed of Nitinol as hereinbefore described is slid over the top of the distal extremity of the conductive layer 307 as shown in Figure 22 to make electrical contact therewith. A polyimide insulating tube 314 having a suitable outside diameter as for example 0.012" is slid over the top of the actuator member 311 and is advanced proximally until it extends over the tapered portion 306a of the insulating layer 306 as shown in Figure 22.

A second actuator member 316 is provided which is formed of Nitinol ribbon having a suitable cross-section as for example a width of 0.004" (4 mils) and a thickness of 0.002" (2 mils). The second actuator member 316 is provided with proximal and distal extremities 317 and 318. An insulating sleeve 319 is provided on the second actuator member 316 and extends over a suitable distance as for example 2.7 cm but leaving portions of the proximal and distal extremities bare so that electrical contact can be made with the second actuator member 316 while still insulating the second actuator member 316 from a coil 321 having proximal and distal extremities 322 and 323 and through which the second actuator member extends The coil 317 is formed of a suitable radiopaque material such as

platinum or a platinum alloy and has a suitable length, as for example 3 cm. The proximal extremity 322 of the coil 321 abuts the distal extremity of the first actuator member 311 in the form of a Nitinol hypotube which is bonded thereto by a conductive solder 326 which also bonds the proximal extremity 317 of the second actuator member 316 to the interior distal extremity of the first actuator member 311 so that it is physically and electrically connected thereto.

In the guide wire shown in Figures 22-23, a binary alloy, as for example Alloy BB is utilized for the first actuator member 311 whereas a ternary alloy, as for example Alloy K, is utilized for the second actuator member 316.

A joining ring 327 formed of a suitable material such as silver is provided and is sized so that it can fit within the distal extremity 323 of the coil 321. A plasma weld 328 then is used to join the joining ring 327 to the distal extremity 323 of the coil 321 and also to form an electrical and physical connection between the distal extremity 304 of the core wire 302 and the distal extremity 318 of the actuator member 316 so that the core wire 302 is electrically connected to one end of the second actuator member 316 which has its other end connected to the first actuator member 311 that is electrically connected to the conductive layer 307. This permits electrical energy to be supplied to the first and second actuator members 311 and 316 by making appropriate connections as hereinbefore described to the bare portion of the proximal extremity of the core wire 302 and the exposed conductive layer 307. A thin layer of a suitable ultra-gviolet cured adhesive 329 is placed over the plasma weld to form a smooth, rounded generally hemispherical surface.

Thus in the guide wire 301 there has been provided a variable stiffness deflectable tip and adjustable deflection guide wire in which an adjustable stiffness

or an adjustable support characteristic can be provided in the shaft portion of the guide wire proximal of the coil 321 to in effect provide an adjustable support. The first and second actuator members 311 and 316 are connected in series so that the current passes through the core wire 302 to the tip of the guide wire 301, through the plasma weld 328, through the Nitinol ribbon forming the second actuator member 316, through the Nitinol hypotube 311, through the conductive layer 307 to the proximal extremity of the guide wire 301 into the electrical connector utilized in connection with the guide wire as hereinbefore described. With this series connection, it is still possible to adjust the stiffness of the shaft and also bend the guide wire at the tip. This is made possible because the Nitinol ribbon forming the second actuator member 316 has a smaller mass than the hypotube forming the first actuator member 311. Thus it is possible to pass sufficient current through the second actuator member 316 to cause deflection of the tip without significantly affecting the stiffness provided by the second actuator member 316. Thus, by appropriately controlling the current flow it is possible to bend the tip by activating the first actuator member 311 and maneuvering the guide wire tip through the tortuous vessel in the body. When it becomes necessary to stiffen the shaft in the vicinity of the coil 321, additional current flow can be applied to cause stiffening of the first actuator member 311 to provide the additional stiffness desired. By way of example, it has been found that 160-200 milliamperes can be utilized for adjusting the bend by activation of the second actuator member 316. The first actuator member 311 can be stiffened by passing additional current, as for example from 200-280 milliamperes and more typically from 220-280 milliamperes.

It should be appreciated that if desired the second actuator member 316 can be formed of Nitinol having a

shape memory corresponding to a predetermined bend which may be desired in the distal extremity of the guide wire tip with the amount of the bend being adjustable by the amount of current flowing through the second actuator member 316. Thus it can be caused to bend in a direction which is perpendicular to the flat side of the ribbon utilized for the second actuator member 316. It also has adjustable stiffness. When it is deactivated, it will lose its stiffness and will be returned to a normally straight position by the force provided by the core wire 302. On the other hand, the first actuator member 311 when deactivated is relatively flexible but normally has a straight configuration which is also the configuration it assumes when it is stiffened as electrical energy is applied to heat the Nitinol alloy.

From the foregoing it can be seen that two separate conductors can be provided that the first actuator member 311 and the second actuator member 316 can be independently controlled. In the guide wire 331 shown in Figures 24 and 25, the conductive layer 307 can be formed to provide two conductors. After the ink conductive layer 307 has been placed, portions of the ink layer 307 are removed or ground away to provide diametrically opposed longitudinally extending slots 332 extending the length of the core wire 302 and through the entire length of the conducting layer 307 to provide two conductive portions 307a and 307b which are insulated from each other. A polyimide insulating layer 333 covers the conductive portions 307a and 307b One of the actuator members, the first actuator member 311, is in physical and electrical contact with conductor 307a of one of the conductors 307a and 307b. The other or second actuator member 316 is in physical and electrical contact with the other conductor 307b of the conductors 307a and 307b. Thus, the first actuator member 311 and second actuator member 316 are electrically isolated from each other. A flexible, ultra-violet cured RTV

adhesive 331 is placed over the coil 321 to permit bending of the coil 321, but closes off the spaces between the coil and serves to prevent blood from entering into the interior of the col during use of the guide wire 341. This prevents cooling of the first and second actuator members during their actuation.

Another embodiment of a guide wire incorporating the present invention is shown in Figures 26-27. This guide wire 341 consists of a core wire 342 of the type hereinbefore described having proximal and distal extremities 343 and 344 as in previous embodiments of the guide wire of the present invention, a polyimide insulating layer 346 is provided which has a tapered portion 346a at its distal extremity which overlies the outer surface of the core wire 342 as shown. A silver conductive layer 348 is provided on the insulating layer 346.

A Nitinol actuator member 351 is provided which is in the form of a ribbon having a rectangular cross-section, as for example a width of 0.004" and a thickness of 0.002". The actuator member 351 is provided with proximal and distal extremities 352 and 353. An insulating cover or coating 354 formed of a suitable material such as a polyimide extends for substantially the entire length of the actuator member 351 but leaving portions of the proximal and distal extremities 352 and 353 bare so that electrical connections can be made therewith. The proximal extremity 352 is physically and electrically bonded to the insulating layer 356 by a silver epoxy joint 356. The silver epoxy forming the joint 356 is cured in a suitable manner as for example for a period of two minutes at 300°F. A polyimide tube 357 extends over the silver epoxy joint 356 and has an outside diameter of 0.012" so as to provide a smooth transition between the tapered portion 346a of the insulating layer 346. A platinum coil 361 has its proximal extremity 362

abutting the polyimide tube 357 and is bonded to the core wire 342 by an epoxy 363. The distal extremity 364 of the coil 361 is secured to the distal extremity of the actuator member 351 and to the distal extremity 344 of the core wire 342 by a plasma weld 366. An ultraviolet-cured adhesive 367 of a suitable type is placed over the plasma weld 366 to provide a rounded tip for the guide wire.

An adhesive material 374 of a suitable type such as an ultravioletly curable silicon RTV type is placed between the turns of the coil 361 and at least enters partially into the space 376 interior of the coil 361 and between the core wire 302. This insulating material 374 serves a dual function. It serves to provide a liquid barrier between the turns of the coil 361 so as to keep blood in the vessel into which the guide wire is introduced from entering into the space 376. By keeping blood out, the insulating material 374 prevents the blood from cooling the actuator member 351 during the time it is activated. The insulating material 374 also serves to conserve heat which is created within the actuator member 351 making it easier for the actuator member 351 to be initially heated and to retain the heat, thereby reducing the overall current flow required and thus making it easier to actuate the tip. The RTV insulating material 374 is desirable because while providing a liquid barrier and heat insulation, it still has great flexibility thereby permitting bending of the distal extremity of the guide wire as hereinbefore described with the previous embodiments.

Operation and use of the guide wire 341 shown in Figures 26-27 is substantially similar to the mode of operation for the guide wires hereinbefore described. The guide wire 341, however, only has the capability for adjusting the stiffness of the coil portion of the guide wire. Thus, a ternary alloy as for example Alloy K can be utilized for the actuator member 351.

In Figure 28, there is shown a cross-sectional view similar to Figure 25 but showing another embodiment of a guide wire of the present invention which, rather than utilizing an actuator member 51 which is rectangular in cross-section there is provided an actuator member 351a which is circular in cross-section and an insulating layer 354a. Such a guide wire can be shaped like a conventional guide wire by the physician placing an appropriate bend in the distal extremity. After the guide wire has been introduced into the vessel in the body, the tip can be stiffened by supplying electrical energy to the actuator member 351a so as to facilitate passing the guide wire through a totally occluded or a substantially occluded vessel.

Additional embodiments of actuator members which can be utilized in place of the actuator member 351 are shown in Figures 29, 30, 31 and 32. Thus, as shown in Figure 29, there is provided an actuator member 381 in the form of a wedge in which the top and bottom surfaces 382 and 383 are in the form elongate rectangles and the side surfaces 384 and 386 are wedge-shaped or tapered. Thus, there will be gradations in stiffness in directions generally perpendicular to the planar surfaces 382 and 383. The actuator member 381 is also provided with a base 387 which is secured to the ink conducting layer 348 and a tip 388 which is embedded within the plasma weld 366. Thus it can be seen that there is additional flexibility provided substantially perpendicularly to the planes formed by the top and bottom surfaces 382 and 383.

In Figure 30 there is shown a triangularly shaped actuator member 391 which is provided with top and bottom surfaces 392 and 393 which are triangular in shape and side surfaces 394 and 396 which are rectangular in shape. It is also provided with a rectangular base 397 which would be bonded to the conductive layer 348 and a tip 398 which would be

embedded in the plasma weld 366. With such an actuator member 391 it can be seen that the degree of bending and/or stiffness also decreases in a direction towards the tip 398.

Another actuator member 401 is shown in Figure 31 and is provided with top and bottom surfaces 402 and 403 which are triangular in shape and side surfaces 404 and 406 which are also triangular in shape. It is also provided with a rectangular base 407 which is bonded to the conducting layer 348 and a tip 408 which is bonded into the plasma weld 366. With such an actuator member 401 it can be seen that the actuator member is tapered in two directions along its length to make possible additional gradations in the stiffness provided by the actuator member 401.

An actuator member 411 shown in Figure 32 consists of top and bottom surfaces 412 and 413 which are triangular in shape and side surfaces 414 and 416 which are also triangular in shape. It is also provided with a square base 417 and a tip 418. Thus it can be seen that the actuator member 411 is in the shape of a pyramid. The base 417 can be bonded to the conducting layer 348 and the tip 418 can be bonded into the plasma weld 366. Thus it can be seen that with the actuator member 411 shown in Figure 32 there is a gradation provided in two directions at right angles to each other which are substantially the same because of the pyramidal shape.

This gradation in cross-sectional area and mass of the actuator member means that progressing towards the tip of the actuator member there is less material for a higher resistance and therefore a higher rate of heating is achieved, making it possible to deflect the distal extremity of the guide wire with a smaller amount of current. This makes it possible to still deflect the tip of the wire or to stiffen the tip of the wire, but also makes it possible to move the point where the wire

starts to bend by moving the point of bending more proximal or more distal depending upon the amount of current which is utilized in activating the actuator member. As the activation current is increased, this current will cause the distal extremity of the guide wire to bend and at the same time will move the radius of bending so that it increases progressively until the bend reaches the proximal extremity of the actuator member. Thus, utilizing the tapered actuator members hereinbefore described, it is possible to change the position of the start of the bend radius. By progressively increasing the current flow through the tapered actuator elements, the commencement of the bend will be moved progressively proximally until the entire actuator member has been incorporated into the bend. Such an adjustable bend location is particularly desirable in traversing particularly tortuous vessels.

It has been found that in connection with the guide wires of the present invention it is possible to ascertain from the proximal extremity of the guide wire whether the guide wire is being activated in air or being activated within a vessel in the human body. This is particularly useful for a physician. The physician wishes to ascertain the characteristics of the distal extremity of the guide wire as it relates to the deflection of the tip or the stiffness of the tip or the stiffness of the distal extremity of the guide wire proximal of the tip coil.

In Figure 33 there is shown a schematic diagram of electrical circuitry utilized for indicating the environment for the distal extremity of the guide wire. In this connection it has been found that the plasma weld, as for example the plasma weld 336 shown in Figure 26 serves as a thermocouple 421 shown in Figure 33. This thermocouple 421 which is provided by the tip plasma weld 366 is connected to the same conductors which supply power to the actuator member 351 which in

the embodiment shown in Figure 26 consists of the core wire 342 and the conductive layer 348 that are connected respectively to lead wires 422 and 423 and connected to an AC power supply 426. The AC power supply 426 provides an AC power output in milliamperes of current at a high frequency sine wave, as for example from 10 kHz to 50 kHz and preferably approximately 33 kHz. The thermocouple 421 generates a DC voltage which can be picked up from the conductors 422 and 423 and supplied through conductors 427 and 428 to a low pass filter 431 to separate the DC voltage from the AC voltage to provide a DC thermocouple voltage output supplied in conductors 432 and 433 to a temperature monitor 436 that provides a reading corresponding to the temperature of the thermocouple 421. From the temperature of the thermocouple 421, the temperature monitor 436 can ascertain whether or not the thermocouple is in air or in the body. If it senses a temperature higher than it normally would be in the body, it is assumed that it is in air and supplies a signal on the conductor 437 to the AC power supply to immediately adjust the AC power supply to an in-air state. This prevents the AC power supply 426 from supplying an unneeded amount of current to the actuator 351 which could possibly damage or destroy the actuator 351. Conversely, if the temperature monitor 436 senses a lower temperature, it then ascertains that the thermocouple 421 must be positioned within the body and causes the AC power supply 426 to be switched to supply additional current to the actuator member 351.

This feature is particularly useful to a physician who is to perform a procedure utilizing a guide wire of the present invention. Assuming that the physician wishes to feel the characteristics of the distal extremity of the guide wire when it is outside the body, the physician can push a switch 438 of the temperature monitor to place the temperature monitor in the air

monitoring mode. The physician by then adjusting the output from the AC power supply 426 can ascertain the stiffness and/or deflection desired at the distal extremity. After the physician has properly adjusted the AC power supply 426 to obtain the proper feel at the distal extremity of the guide wire, the physician again operates the switch 438 to return the temperature monitor to its automatic mode at which time it will scale up the current supplied from the AC power supply 426 to provide the same characteristics at the distal extremity of the guide wire as the physician was able to feel when the guide wire was outside of the body.

In view of the foregoing it can be seen that there has been provided a guide wire which has many desirable features. The guide wire has a deflectable tip which can be deflected or bent from a remote location. The deflectable tip can have a shape memory incorporated therein which can be brought into play by the application of heat to the distal extremity. Different bends can be provided in the distal extremity. Also increased stiffness can be achieved. This makes the guide wire of the present invention very advantageous for use in traveling through tortuous vessels and for passing through totally occluded or substantially occluded vessels. Procedures can be accomplished without withdrawing the guide wire from the vessel. Similarly, stenoses in different vessels can be addressed without completely withdrawing the guide wire or reshaping the distal extremity of the guide wire after it has been withdrawn. The guide wire also has very desirable characteristics such as being very floppy with a soft atraumatic tip. Also when desired the distal extremity can be activated to achieve additional stiffness in the distal extremity to facilitate crossing a stenosis.

Also in connection with the guide wires of the present invention it is possible to provide an

additional actuator member. Such an additional actuator member is located the guide wire just proximal of the coil to provide additional stiffness and support from the guide wire. This is particularly useful when the guide wire is utilized with a balloon catheter or a stent delivery catheter in which it is desired to impart additional rigidity to the catheter. This can be readily accomplished by activating the additional actuator member to provide the additional stiffness which is translated through the balloon catheter to aid in having the balloon catheter cross a stenosis or to aid in the delivery of a stent carried by the stent delivery catheter, particularly when it is desired to advance the stent into a desired region in the stenosis. Additional capabilities are provided for ascertaining whether the guide wire is in air or in the body to facilitate setting the desired characteristics for the guide wire. The feel which the physician sets in air or outside the body can be achieved within the body.

In connection with the present invention it should be appreciated that although the electrical energy is supplied directly to the actuator members, it is possible to provide a separate heating element adjacent each actuator member for heating the actuator member.

WHAT IS CLAIMED IS:

1. A guide wire for use in a medical procedure and for use with a power supply comprising a solid core wire having proximal and distal extremities, the proximal extremity having a predetermined diameter, at least a portion of the distal extremity having a reduced size with respect to the predetermined diameter, a flexible coil secured to the distal extremity of the core wire and extending over the portion of the core wire having a reduced size, an actuator member disposed proximal of the coil and extending along the core wire, electrical conductive means extending from the proximal extremity of the core wire and to the actuator member for supplying heat to the actuator member, said actuator member being formed of a temperature activated metal alloy having a Young's modulus of 4×10^6 to 14×10^6 psi which increases in stiffness when heat is supplied thereto to increase the stiffness of the guide wire proximally of the coil.

2. A guide wire as in Claim 1 wherein said actuator member is in the form of a cylindrical tube encircling the core wire.

3. A guide wire as in Claim 1 wherein said electrical conductive means is connected to opposite ends of the cylindrical tube.

4. A guide wire as in Claim 1 wherein said temperature activated metal alloy is a binary alloy.

5. A guide wire as in Claim 4 wherein said binary alloy is Alloy BB.

6. A guide wire as in Claim 1 further including an additional actuator member disposed within the coil and extending longitudinally of the core wire and means carried by the core wire for electrically connecting the additional actuator member to the power supply from the proximal extremity of the guide wire.

7. A guide wire as in Claim 6 wherein said additional actuator member is formed of a shape memory nickel titanium alloy.

8. A guide wire as in Claim 7 wherein said shape memory nickel titanium alloy is a ternary alloy.

9. A guide wire as in Claim 8 wherein said ternary alloy is Alloy K.

10. A guide wire as in Claim 6 wherein said first named and additional actuator members are connected in series.

11. A guide wire as in Claim 6 wherein said first named and additional actuator members are connected in parallel.

12. A guide wire as in Claim 1 wherein said core wire serves as one conductor and wherein the other conductor is provided by a conductive layer formed on the core wire exterior of the core wire.

13. A guide wire as in Claim 1 wherein said power supply is an AC power supply and wherein said means connecting the distal extremity of the core wire to the distal extremity of the coil provides a thermocouple generating a DC current when electrical energy is supplied to the actuator member to heat the same and further including means filtering the DC voltage generated by the thermocouple from the AC power supply to provide a voltage representative of the temperature of the thermocouple.

14. A guide wire as in Claim 6 wherein said additional actuator member has proximal and distal extremities and wherein said additional actuator member is formed so that it has a decreasing mass in a direction extending from the proximal extremity to the distal extremity to provide a guide wire in which the bend location in the second actuator member can be adjusted by adjusting the current flow through the additional actuator member.

15. A guide wire having a distal extremity with an adjustable support characteristic comprising a core wire having proximal and distal extremities, said distal extremity having a reduced cross sectional area to provide a distal extremity which is more flexible than the proximal extremity, means forming a tip secured to the distal extremity of the core wire, a sleeve of temperature activated metal alloy coaxially disposed on the distal extremity of the core wire, said sleeve being annealed so it is relatively flexible at a temperature ranging from 20° to 40°C and becomes progressively stiffer as temperature increases, conductive means carried by the core wire for conducting electrical energy to the superelastic sleeve for supplying heat to the sleeve and extending from the proximal extremity of the core wire to the sleeve to cause the sleeve to

become stiffer to thereby increase the stiffness of the distal extremity of the guide wire whereby a guide wire is provided having a distal extremity with an adjustable support characteristic which varies from a floppy characteristic to a stiff characteristic.

16. A guide wire as in Claim 15 wherein said temperature activated metal alloy is a nickel-titanium alloy.

17. A guide wire as in Claim 15 wherein said means for supplying electrical energy to the superelastic sleeve consists of a layer of conductive material insulated from the core wire extending from the proximal extremity of the core wire to the sleeve and making electrical contact with the proximal extremity of the sleeve and means for establishing an electrical connection between the distal extremity of the superelastic sleeve and the core wire.

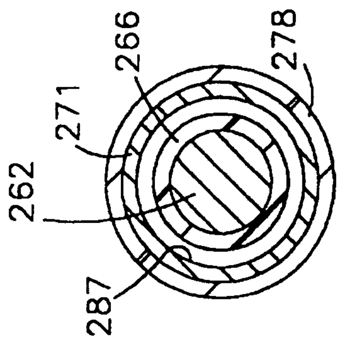

FIG.20

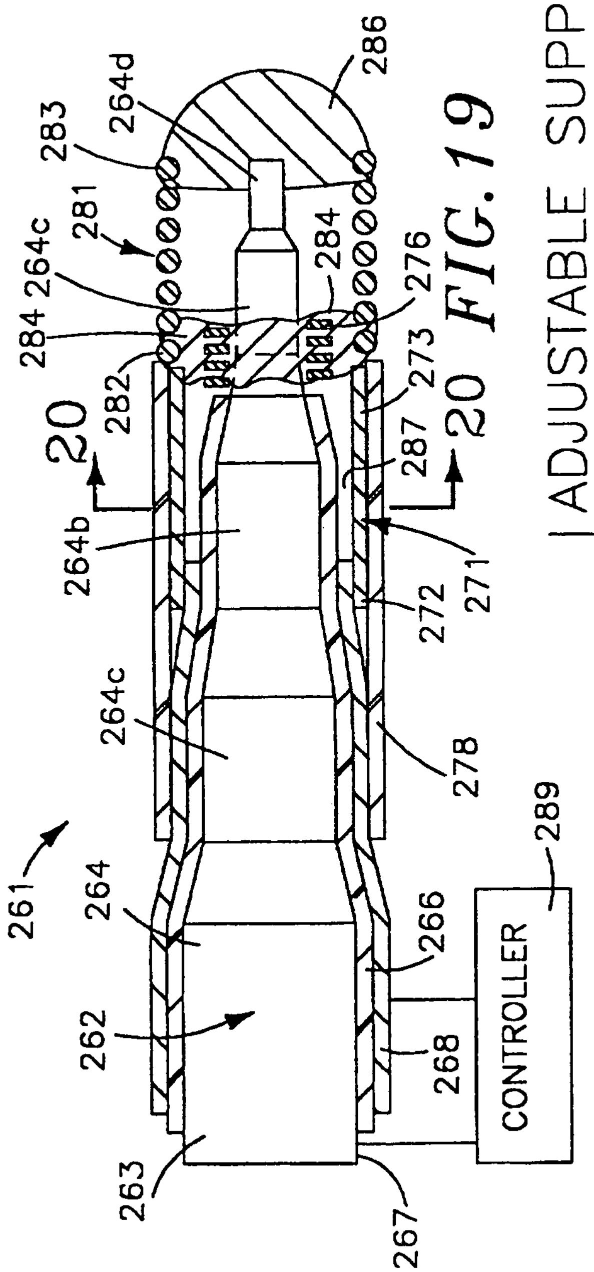

FIG.19

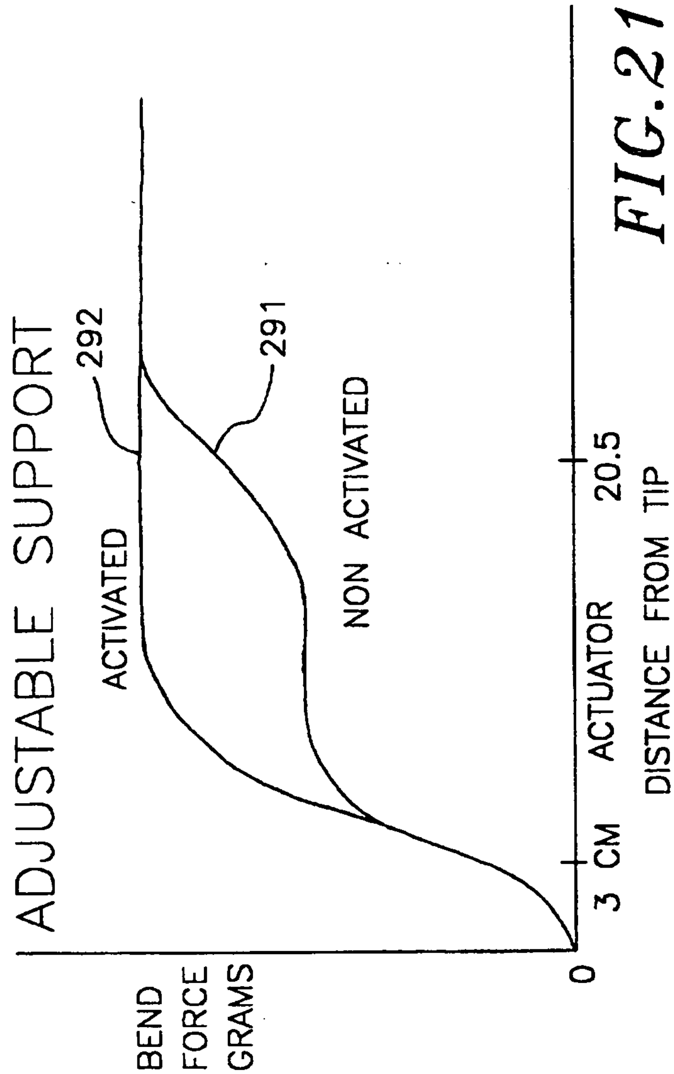

FIG.21

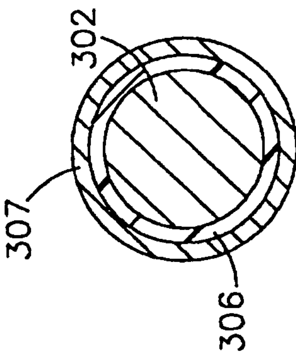

FIG.23

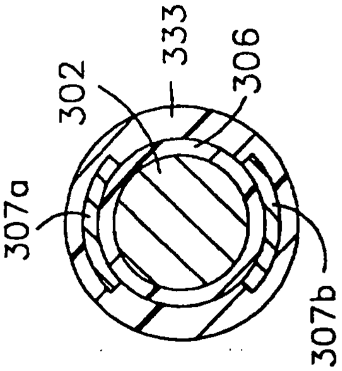

FIG.25

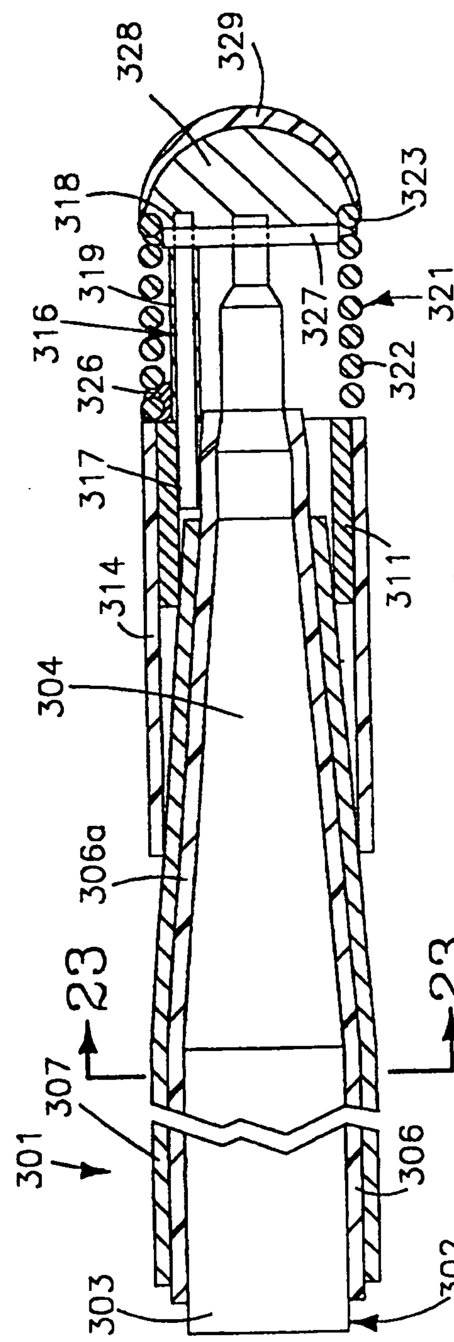

FIG.22

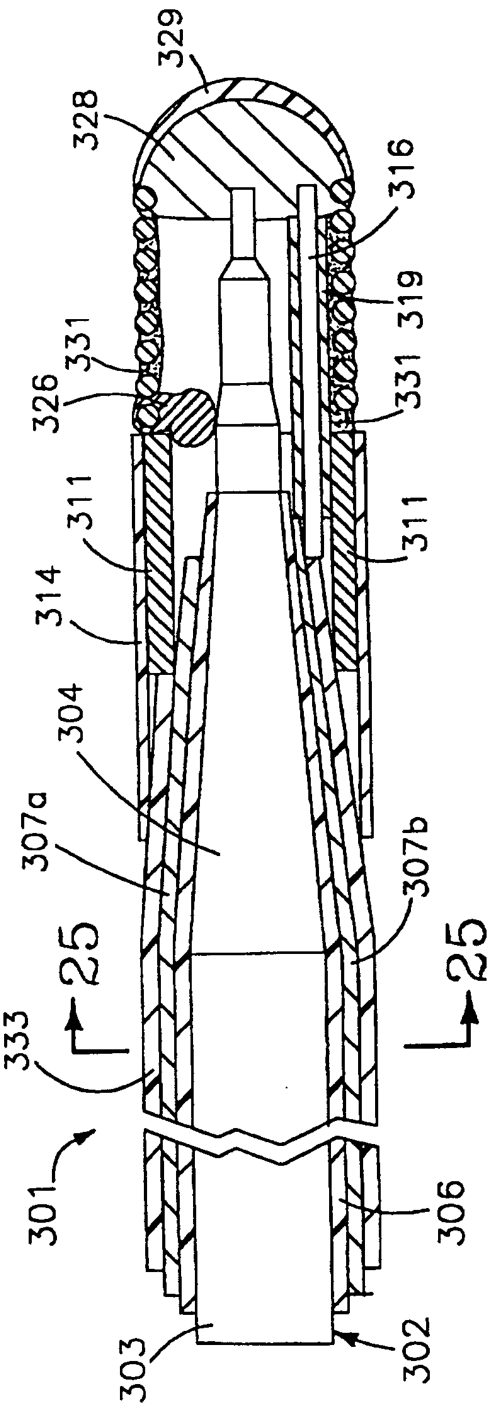

FIG.24

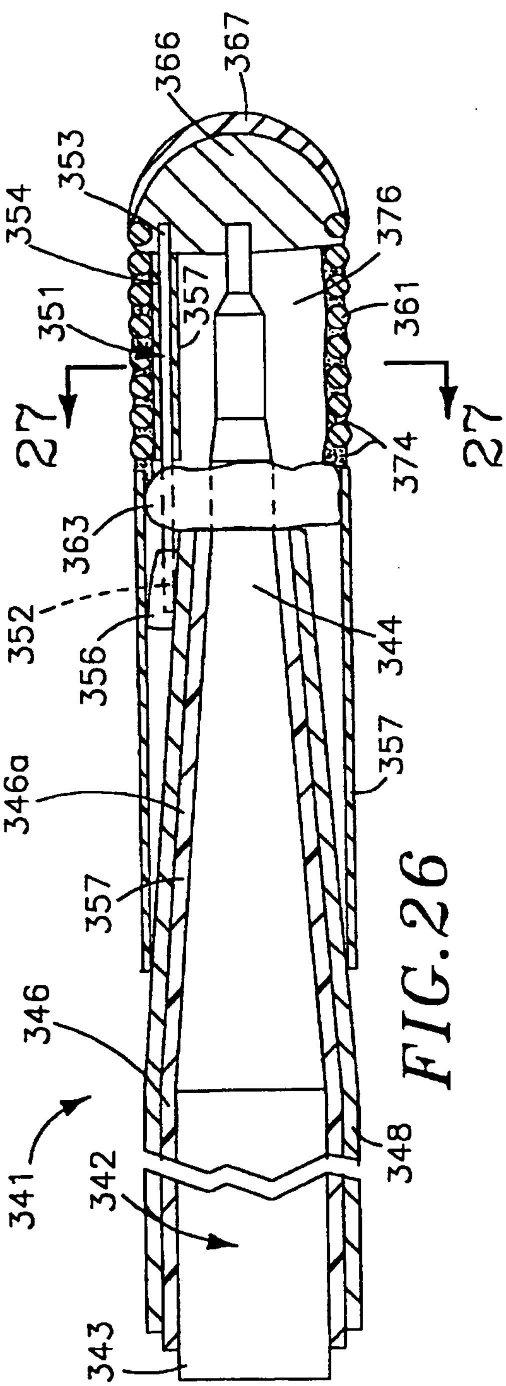

FIG.26

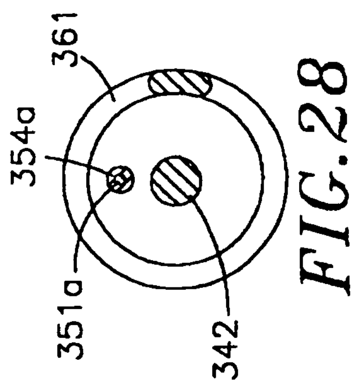

FIG.28

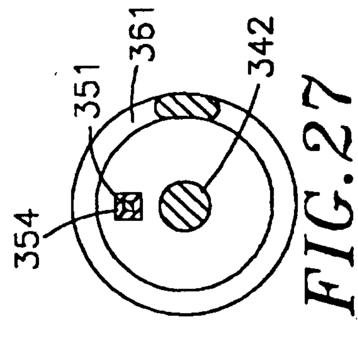

FIG.27

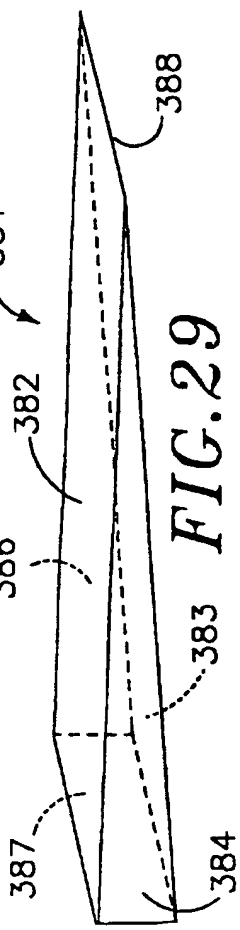

FIG.29

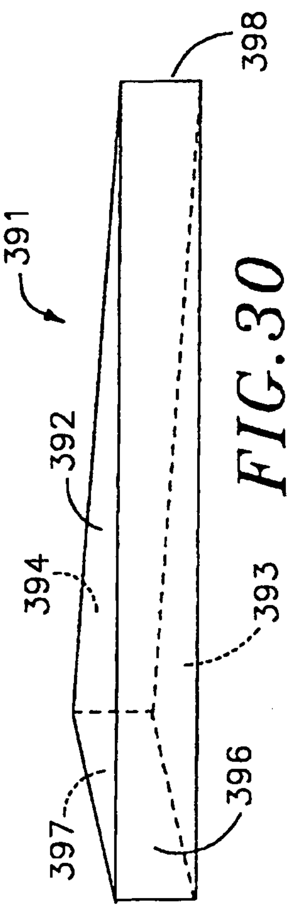

FIG.30

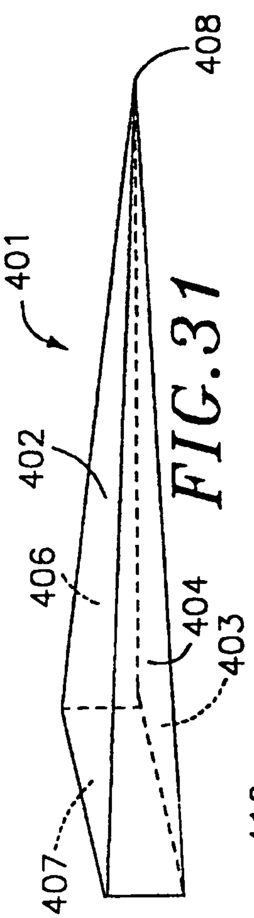

FIG.31

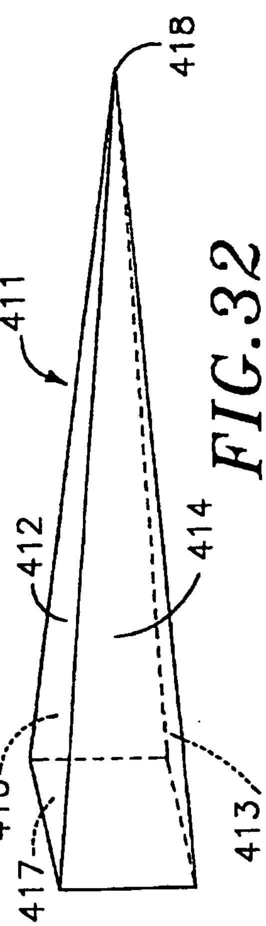

FIG.32

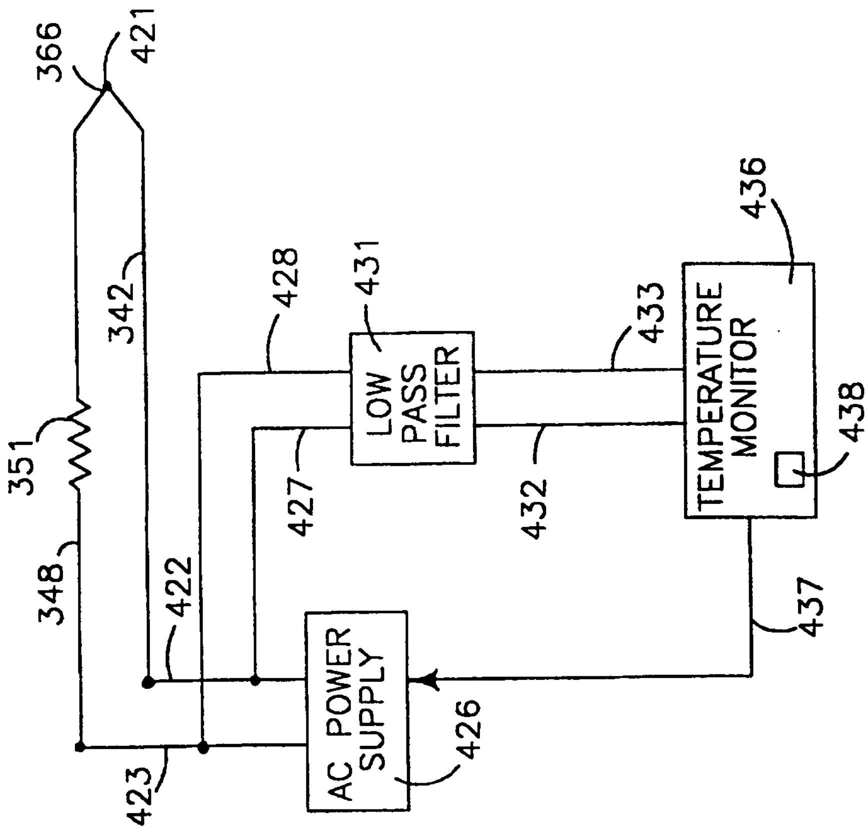

FIG.33

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/00316

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 5/00
US CL :128/772
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/657, 658, 772; 604/95, 96, 280-283

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,349,964 A (IMRAN et al) 27 Septermber 1994, cols. 5 and 6; col. 3, lines 17-25; and Figs. 6-8.	1-12, 14-17
Y	US 5,341,818 A (ABRAMS et al) 30 August 1994, Fig.1.	1-12, 14-17
Y	US 5,025,799 A (WILSON) 18 May 1993, col. 5, lines 5-34.	1-12
Y	US 4,961,433 A (CHRISTIAN) 09 October 1990, col. 5, lines 44-62.	2, 3, 15-17

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 APRIL 1997	12 MAY 1997

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